ISRCTN40568538 https://doi.org/10.1186/ISRCTN40568538

SMaRT oncology-2: a two arm parallel group randomised controlled trial to determine the effectiveness and cost-effectiveness of adding a complex intervention for major depressive disorder ('Depression Care for People with Cancer') to usual care, compared to usual care alone in cancer patients

Submission date
13/05/2008

Recruitment status
No longer recruiting

Registration date
30/05/2008

Overall study status
Completed

Last Edited
04/04/2022

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-treating-depression-people-with-cancer-smart-oncology-2

Contact information

Type(s)
Scientific

Contact name
Prof Michael Sharpe

Contact details
School of Molecular and Clinical Medicine
The University of Edinburgh
Kennedy Tower
Royal Edinburgh Hospital
Morningside Park
Edinburgh
United Kingdom

EH10 5HF
+44 (0)131 537 6672
michael.sharpe@ed.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
v1.1 12/05/08

Study information

Scientific Title
SMaRT oncology-2: a two arm parallel group randomised controlled trial to determine the effectiveness and cost-effectiveness of adding a complex intervention for major depressive disorder ('Depression Care for People with Cancer') to usual care, compared to usual care alone in cancer patients

Acronym
SMaRT (Symptom Management Research Trials)

Study objectives
1. 'Depression Care for People with Cancer' as a supplement to usual care will be more effective than usual care alone in achieving a 50% reduction in baseline 20-item depression score from the Symptoms Checklist (SCL-20D) at 24 weeks
2. 'Depression Care for People with Cancer' as a supplement to usual care will cost more than usual care alone but will be more cost effective in achieving improvements in patients depression and quality of life

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scotland A research ethics committee, 31/03/2008, ref: 08/MRE00/23

Study design
Multicentre randomised controlled two-arm parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Depression in patients with cancer

Interventions
Patients will be randomised to receive:
1. Usual care, or
2. Usual care plus 'Depression Care for People with Cancer'

Usual care arm:
The usual care of depression from the patient's GP or oncologist (this is routine care and won't be influenced by the researchers)

Usual care plus 'Depression Care for People with Cancer' arm:
In addition to usual care as above a complex intervention for depression delivered by a specially trained cancer nurse under the supervision of a psychiatrist, a maximum of 10 treatment sessions delivered over 16 weeks followed by monthly monitoring of progress until 12 months. The intervention comprises education about depression and its treatments (including antidepressant medication, which would be prescribed by the GP if the patient wishes to take it, and behavioural activation) and problem solving treatment.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Treatment response, measured at 24 week outcome data collection, defined as a reduction of 50% or more in the patients baseline SCL-20D score

Secondary outcome measures
1. Remission of major depressive disorder, defined as an SCL-20D score of less than 0.75 at each of 24, 36 and 48 weeks (higher than in primary care trials, to allow for cancer-related somatic symptoms)
2. Depression severity, defined for each patient as the average of their SCL-20D score at 24, 36 and 48 weeks

Overall study start date
15/05/2008

Completion date
01/06/2011

Eligibility

Key inclusion criteria
Patients must:
1. Have a diagnosis of cancer, with active disease within the last five years
2. Be aged 18 or over, either sex
3. Be attending a specialist oncology clinic
4. Have a predicted survival, estimated by their cancer specialist, of twelve months or more
5. Have symptoms that meet Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) criteria for major depressive disorder (MDD), with symptoms of the current major depressive episode (MDE) present for four weeks or more using the inclusive approach to diagnosis

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

Total final enrolment
500

Key exclusion criteria
1. Patients are unable to provide informed consent to participate
2. The episode of depression is chronic (defined as a history of continuous depression for at least two years)
3. They are judged to require urgent psychiatric care
4. They are receiving active psychiatric or psychological treatment from specialist mental health services
5. They have cognitive impairment or communication difficulties (including inability to adequately understand verbal explanations or written information in English) which are incompatible with the intervention
6. They have known cerebral metastases
7. They are unable to attend regularly for treatment sessions
8. The intervention is judged to be inappropriate due to a medical condition which requires alternative treatment
9. The intervention is judged to be inappropriate due to a psychiatric condition which requires alternative treatment (psychotic illness, bipolar affective disorder, obsessive compulsive disorder, substance abuse or dependence)
10. Their participation in the trial is judged to be inappropriate on other clinical grounds

N.B. Patients receiving active cancer treatments will not be excluded unless they fulfil one or more of the exclusion criteria listed above.

Date of first enrolment
15/05/2008

Date of final enrolment
01/06/2011

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
The University of Edinburgh
Edinburgh
United Kingdom
EH10 5HF

Sponsor information

Organisation
University of Edinburgh

Sponsor details
c/o Marise Bucukoglu
Associate Director (Governance & Sponsorship)
Edinburgh Clinical Trials Unit
Queens Medical Research Institute
47 Little France Crescent
Edinburgh
Scotland
United Kingdom
EH16 4TJ
+44 (0)131 242 9262
marise.bucukoglu@ed.ac.uk

Sponsor type
University/education

Website
http://www.ed.ac.uk/

ROR
https://ror.org/01nrxwf90

Organisation
NHS Lothian - University Hospitals Division (UK)

Sponsor details
Research & Development Office
Royal Infirmary of Edinburgh
51 Little France Crescent
Edinburgh
Scotland
United Kingdom
EH16 4SA

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	30/03/2009		Yes	No
Results article	results	20/09/2014		Yes	No
Results article	results	01/12/2015		Yes	No
Plain English results			04/04/2022	No	Yes